DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 8, 2014

EOSHEALTH, INC.
CARRIE HETRICK
SENIOR CONSULTANT, RA, C/O EMERGO GROUP
816 CONGRESS AVE, STE 1400
AUSTIN, TX 78701

Re: k133584
Trade/Device Name: In Touch Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA, JJX
Dated: August 26, 2014
Received: August 27, 2014

Dear Ms. Hetrick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k133584

Device Name
In Touch® Blood Glucose Monitoring System

Indications for Use *(Describe)*
The In Touch® Blood Glucose Monitoring System (In Touch® BGMS) is an over-the-counter (OTC) device utilized by persons with diabetes in home settings for the quantitative measurement of glucose in fresh whole capillary blood from the fingertip. It is intended for use by people with diabetes mellitus at home as an aid to monitor the effectiveness of diabetes control program. The In Touch® BGMS is for in vitro diagnostic use only and should not be used for the diagnosis of /or screening for diabetes mellitus or neonatal use. The In Touch® BGMS is intended to be used by a single person and should not be shared.

The In Touch® Blood Glucose Test Strips (In Touch® strips) are used with the In Touch® Blood Glucose Meter (In Touch® meter) in the quantitative measurement of glucose in fresh capillary blood from the fingertip.

The In Touch® Control Solution is for use with the In Touch® meter and In Touch® strips as a quality control check to verify that the meter and test strips are working together properly and that the test is performing correctly.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

for

In Touch® Blood Glucose Monitoring System

1. Submission Submitter

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Email: project.management@emergogroup.com

3. Date Prepared

September 4, 2014

4. Proprietary and Established Names

In Touch® Blood Glucose Monitoring System

5. Regulatory Information

Trade / Proprietary Name	Classification	Regulation Section	Product Code	Panel
In Touch® Blood Glucose Monitoring System	Class II	21 CFR § 862.1345	NBW; System, Test, Blood Glucose, Over The Counter	Clinical Chemistry (75)
In Touch® Blood Glucose Meter (In Touch® Meter)	Class II	21 CFR § 862.1345	NBW; System, Test, Blood Glucose, Over The Counter	Clinical Chemistry (75)
In Touch® Blood Glucose Test Strips (In Touch® Strips)	Class II	21 CFR § 862.1345	CGA; Glucose Oxidase, Glucose	Clinical Chemistry (75)

Trade / Proprietary Name	Classification	Regulation Section	Product Code	Panel
In Touch® Control solution	Class I	21 CFR § 862.1660	JJX; Single (Specified) Analyte Controls (Assayed And Unassayed)	Clinical Chemistry (75)

6. Indication for Use Statement

The In Touch® Blood Glucose Monitoring System (In Touch® BGMS) is an over-the-counter (OTC) device utilized by persons with diabetes in home settings for the quantitative measurement of glucose in fresh whole capillary blood from the fingertip. It is intended for use by people with diabetes mellitus at home as an aid to monitor the effectiveness of diabetes control program. The In Touch® BGMS is for in vitro diagnostic use only and should not be used for the diagnosis of /or screening for diabetes mellitus or neonatal use. The In Touch® BGMS is intended to be used by a single person and should not be shared.

The In Touch® Blood Glucose Test Strips (In Touch® strips) are used with the In Touch® Blood Glucose Meter (In Touch® meter) in the quantitative measurement of glucose in fresh capillary blood from the fingertip.

The In Touch® Control Solution is for use with the In Touch® meter and In Touch® strips as a quality control check to verify that the meter and test strips are working together properly and that the test is performing correctly.

7. Device Description

The EosHealth, Inc. In Touch® BGMS, is an Over-The-Counter (OTC) system designed for the self-monitoring of blood glucose by persons with diabetes in home settings to aid in their diabetes management. The system consists of the following components:

- In Touch® Blood Glucose Meter (In Touch® meter)
- In Touch® Blood Glucose Test Strips
- In Touch® Lancing Device
- In Touch® Lancets
- In Touch® Level 1 Control Solution
- In Touch® Level 2 Control Solution
- AC Adapter (wall charger) and USB Charger
- Carrying Case
- In Touch® Data Management System (optional accessory to the In Touch® BGMS)

The In Touch® meter is an Over-The-Counter (OTC), handheld device that along with the primary components of the system, monitors glucose in the blood to help with the management and treatment of diabetes. The In Touch® meter also incorporates additional features to aid in self-monitoring of blood glucose including tables and logs, graphs, and a pedometer.

The test principle is based on electrochemical biosensor technology and the principle of capillary action. The electrical current generated by the reaction of glucose with the reagent of the strip is measured by the meter and is displayed as the corresponding blood glucose

level. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample. These blood glucose measurements are obtained through the use of disposable test strips.

These blood glucose levels are displayed on the screen and stored in In Touch® meter's memory. In addition to the immediate read-out on In Touch® meter's display, the readings can also be transmitted securely over the GSM cellular network to a secure server. The use on the GMS connection also provides the ability for direct feedback from the server to the In Touch® meter.

8. Legally Marketed Predicate Device(s)

ACON Laboratories, Inc. On Call® Vivid Blood Glucose Monitoring System, 510(k) Number k112653
ACON Laboratories, Inc. On Call® Diabetes Management Software, 510(k) Number k101371

9. In Touch® Substantial Equivalence Discussion

The comparison chart below provides information to demonstrate the substantial equivalence between the In Touch® Blood Glucose Monitoring System to the predicate device, the ACON On Call® Vivid Blood Glucose Monitoring System (k112653) with respect to intended use, technological characteristics, and principles of operation.

Table 1: Comparison of In Touch® Characteristics with Predicate Device

Comparator	EosHealth, Inc.	ACON Laboratories, Inc.
Trade Name	In Touch® Glucose Monitoring System	On Call® Vivid Glucose Monitoring System
510(k) Number	k133584	k112653
Product Code	NBW - System, Test, Blood Glucose, Over the Counter	NBW - System, Test, Blood Glucose, Over the Counter
Regulation Number	21 CFR § 862.1345	21 CFR § 862.1345
Panel	Clinical Chemistry (75)	Clinical Chemistry (75)
Over-the-Counter (OTC) and/or Rx	OTC	OTC
Indications for Use	The In Touch® Blood Glucose Monitoring System (In Touch® BGMS) is an over-the-counter (OTC) device utilized by persons with diabetes in home settings for the quantitative measurement of glucose in fresh whole capillary blood from the fingertip. It is intended for use by people with diabetes mellitus at home as an aid to monitor the effectiveness of diabetes control program. The In Touch® BGMS is for in vitro diagnostic use only and should not be used for the diagnosis of /or screening for diabetes mellitus or neonatal use. The In Touch® BGMS is intended to be used by a single person	The On Call® Vivid Blood Glucose Monitoring System uses an electrochemical enzymatic assay for the quantitative detection of glucose in fresh capillary whole blood from the fingertip, forearm, and palm by people with diabetes at home as an aid in monitoring the effectiveness of diabetes control programs. Alternate testing sites (forearm and palm) should be used only during steady-state times (when blood glucose level is not changing rapidly). The On Call®) Vivid Blood Glucose Monitoring System is intended to be used by a single patient and should not be used for testing

Comparator	EosHealth, Inc.	ACON Laboratories, Inc.
	and should not be shared. The In Touch® Blood Glucose Test Strips (In Touch® strips) are used with the In Touch® Blood Glucose Meter (In Touch® meter) in the quantitative measurement of glucose in fresh capillary blood from the fingertip. The In Touch® Control Solution is for use with the In Touch® meter and In Touch® strips as a quality control check to verify that the meter and test strips are working together properly and that the test is performing correctly.	multiple patients. It is for in vitro diagnostic use only. The On Call® Vivid Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes mellitus or neonatal use. The On Call® Vivid Blood Glucose Test Strips are used with the On Call Vivid Blood Glucose Meter in the quantitative measurement of glucose in fresh capillary blood from the fingertip, forearm, and palm. The On Call® Vivid Blood Glucose Control Solution is for use with the On Call® Vivid Blood Glucose Meter and Test Strips as a quality control check to verify that the meter and test strips are working together properly and that the test is performing correctly.
Intended Users	Adults and Children	Adults and Children
Blood Glucose Meter	In Touch® meter	On Call® Vivid meter
Test Strip	In Touch® Blood Glucose Test Strip*	ACON On Call® Vivid Blood Glucose Test Strip (k112653)
Control Solution	In Touch® Level 1 and Level 2 Control Solution*	On Call® Level 1 and Level 2 Control Solution
AC Adapter	AC Adapter (wall charger)**	None
USB Charger	USB Charger**	None
Carrying Case	Carrying Case**	Carrying Case
Technical Support	Yes	Yes
User's Manual	Available on Internet while using program	Available on Internet while using program
Glucose Methodology	Electrochemical enzymatic assay, Glucose Oxidase	Electrochemical enzymatic assay, Glucose Oxidase
Glucose Test Results	mg/dL (Plasma values)	mg/dL (Plasma values)
Sample	Fresh Capillary whole blood	Fresh capillary whole blood
Blood Source	Fingertip	Fingertip, Forearm, Palm
Glucose Minimum Sample Volume	0.8 µL	0.8 µL
Glucose Test Range	20 to 600 mg/dL (1.1-33.3 mmol/L)	20 to 600 mg/dL (1.1-33.3 mmol/L)
Length of Test	5 seconds	5 seconds
Glucose Test Strips Active Reagent	Glucose Oxidase	Glucose Oxidase
Test Strip Calibration Coding	No Code	No Code

Comparator	EosHealth, Inc.	ACON Laboratories, Inc.
Glucose Test Imprecision	6% or 5.4 mg/dL (whichever is greater) CV @<75 mg/dL=4.59%; CV @>75 mg/dL 3.68%	6% or 5.4 mg/dl (whichever is greater)
Glucose Test Linearity	From 20-600 mg/dL 95% CI, r^2=0. 9986; mean slope 1.004±0.008 (95% CI), intercept 2.36	From 20-600 mg/dL 95% CI, r^2=0.988; mean slope 0.99, intercept 6.0
Glucose Test Accuracy	<75 mg/dL 100% are within ±15 mg/dL; >75 mg/dL 99.7% within ±15 %	<75 mg/dL 100% are within ±15 mg/dL; >75 mg/dL 100% within ±15 %
Acceptable Hematocrit Range	20% to 70%	20% to 70%
Meter Operating Temperature	41°F to 113°F (5°C to 45°C)	41°F to 113°F (5°C to 45°C)
Meter Operating Relative Humidity	10% to 90% non-condensing	10% to 90% non-condensing
Operating Altitude	Up to 8,546 ft. (2,595 m)	Up to 8,546 ft. (2,595 m)
Dimensions	3.6 x 2.3 x 0.9 in (91.4 x 58.4 x 22.9 mm)	3.58" x 2.28" x 0.83"
Weight	2.65 oz. (75 g)	Approximately 60 g (without battery installed)
Display language	English	English
Data display	Numerical & Icons	Numerical & Icons
Display	Color LCD-Touch	B & W LCD
Data Output Port	GPRS Telit 865 QUAD GSM	USB, 9600 baud, 8 data bits, 1 stop bit, no parity
Monitor data storage	1000 results with time and date	500 results with time and date
Day average	7-, 14-, 30-, 60-, 90- day average glucose result	7-, 14-, 30-, 60-, 90- day average glucose result
Insulin Logging	Yes	No
Pedometer	Pedometer	Not applicable
Battery Type	3.7 Li-Polymer Battery 1100 mAh, rechargeable, permanently installed	Two (2) CR 2032 3.0V coin cell batteries, 250 mA
Battery Charge Time	2 hours	Not applicable
Rated	IEC 61010-1, IEC 61010-2-101, IEC 61326	IEC 61010-1, IEC 61010-2-101, IEC 61326
Test Strips Storage Temperature Range	41°F to 86°F (5°C to 30°C)	41°F to 86°F (5°C to 30°C)

The In Touch® Blood Glucose Monitoring System's Indications for Use statement is similar to the predicate device with minor variation. The device also has similar technological characteristics as the predicate device with minor variation. Both devices have similar firmware and utilize the same blood glucose test strips, lancing devices, lancets, and control solution. The data collection software functionality, communication method with data

management software functionality, communication method with the central server, implementation method of collecting data from the test strips, monitor software, connectivity, and communication are similar to the predicate device with minor variation. The subject and predicate devices use exactly the same firmware embedded in the same microcontroller that recognizes the same blood glucose strip, and no other, the same algorithm to calculate blood glucose, and all corrections including those for hematocrit.

Although the In Touch® device differs with a more vibrant and easier to use user interface, uses plain language rather than "device" codes, easy to find control buttons, icons, and a 16-bit color touch display, it is very similar in all other electronic, and technological characteristics related to blood glucose measurements of the predicate devices to assure equivalence. Performance data are provided to support this. The results of all non-clinical and clinical performance testing demonstrate substantial equivalence.

10. Non-Clinical Performance Characteristics

Non-clinical testing was conducted on the In Touch® and to show substantial equivalence to the predicate device:

- Software verification and validation testing (IEC 62304, FDA Guidance, 5/2005)
- Electromagnetic Compatibility Study (ISO 15197, IEC 61326-1)
- Electrical Safety testing (IEC 61010-1, IEC 61010-2-101, IEC 62133, UL 61010-1, CSA C22#61010-1)
- Cleaning and Disinfection testing (FDA Guidance, 1/2014)
- Precision Evaluation (ISO 15197)
- Linearity Evaluation (ISO 15197)
- Accuracy Evaluation (non-user) (ISO 15197)
- Hematocrit Evaluation (ISO 15197)
- Interference Study (CLSI EP7-A2)
- Operating Temperature and Humidity Study (ISO 15197)
- Robustness Evaluation (FDA Guidance, 1.2014)
- FLEX Studies: Vibration and Drop Testing (FDA Guidance, 1/2014)
- Human Factors Studies (FDA Guidance, 6/2011)
- Transport Packaging (ISTA Standard 2A)

Testing demonstrated the In Touch® Blood Glucose Monitoring System meets all relevant standards requirements. Internal verification and validation testing confirms that the product specifications are met which are equivalent in design and technological characteristics to the predicate device. The testing results support that the disinfection, electrical safety testing, and functional testing of the monitor all met or exceeded the standards for the acceptance of the device. Testing of the In Touch® Blood Glucose Monitoring System supports the claims of substantial equivalence to the predicate device. Evaluation of the performance characteristics establishes that the performance, functionality and reliability of the In Touch® Blood Glucose Monitoring System are substantially equivalent to the predicate device. The evaluation included precision, linearity, accuracy, humidity and temperature, and hematocrit. The In Touch® Data Management System (DMS) (optional) software verification and validation demonstrated safety and effectiveness of the In Touch® DMS remote database and substantial equivalence to the predicates ACON On Call® Diabetes Management Software (k101371).

Software: All documentation was prepared and submitted for the device in accordance with FDA guidance documents. The software was tested against the established Software Design Specifications for each of the test plans to assure the device performs as intended. The device Hazard analysis was completed, and risk control implemented to mitigate identified hazards. The testing results support that all the software specifications have met the acceptance criteria of each module and interaction of processes. The In Touch® Blood Glucose Monitor System device passed all testing and supports the claim of substantial equivalence and safe operation.

Electrical safety: The In Touch® Blood Glucose Monitoring System device complies with the applicable voluntary standards for Electromagnetic Compatibility, and Electrical Safety. The device passed all the electrical and safety testing according to national and international standards including IEC 61010-1 and IEC 61010-2. The Li-polymer battery is certified to IEC 62133 standards for medical devices.

Electromagnetic interference: The In Touch® Blood Glucose Monitoring System device has been tested and successfully met all of the relevant sections (Radiated Emissions, Electro Static Discharge Immunity Test, Radiated Radio-Frequency Electromagnetic Immunity, and Power Frequency Magnetic Field Immunity Test) to complies to all standards including EN 55011 ISM RF, IEC 60601-1-2, IEC 60610-1, IEC 60610-2-101, EN 6100-3-2 EMC, EN 6100-3-3 EMC Part 3-3, IEC 61326-1, and IEC 61326-2-6.

Disinfection/Cleaning: The In Touch® Blood Glucose Monitoring System device is intended for single-patient use. Disinfection studies showed that Dispatch® Hospital Cleaner Disinfectant Towels with Bleach disposable wipes (EPA Reg. No: 56392-8) were effective in reducing the risk of blood borne pathogens, particularly hepatitis B virus (HBV). The studies showed complete inactivation of live virus for use with the meter and lancing device.

Precision Evaluation: The In Touch® meter was evaluated in accordance with NCCLS EP5-A User Evaluation of Precision Performance of Clinical Chemistry Devices and ISO 15197:2013. The subject device within-run and between-run tests over the blood glucose concentration range of 20-600 mg/dL and Control Levels 1 and 2 showed less than 1.5% coefficient of variation within runs and between runs compared to the mass spectrometry and/or YSI reference standards over the course of ten days and less than 1.5% coefficient of variation with the predicate device.

Linearity Evaluation: The In Touch® meter was tested to determine the linearity in accordance with CLSI document EP6-A, "Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach" v23, no 16, and ISO 15197: 2003. The In Touch® meter was shown to demonstrate high linearity over the range 10.46 mg/dL to 672.9 mg/dL. The claimed blood glucose measuring range is 20 to 600 mg/dL, as with the predicate device. Linear regression showed a correlation of r^2=0.9995 compared to the mass spectrometry reference standard and correlation of r^2=0.9988 with the predicate device over the range 24 mg/dL to 560 mg/dL, and a correlation coefficient of r^2= 0.9986 over the range 10.46 mg/dL to 672.9 mg/dL compared to the YSI STAT standard reference.

Accuracy Evaluation (non-user): The In Touch® meter was evaluated for accuracy (non-user) using YSI as the reference standard. The In Touch® meter was 100% accurate within ±15

mg/dL at blood glucose concentrations <75 mg/dL and 100% within ± 15 mg/ml and blood glucose concentrations ≥75 mg/dL 99.7% within ±15 mg/dL meeting accuracy acceptance criteria.

Hematocrit Evaluation: The effect of varying hematocrit levels on the performance of the In Touch® meter was evaluated over a hematocrit range of 20-70% hematocrit and compared to the predicate. As for the predicate the results validated the range of 20% to 70% for the In Touch® meter, with a percent bias less than 8% across all ranges of hematocrit and within the glucose concentration range from 40 mg/dL to 550 mg/dL.

Analytical Specificity: The interference study was completed by ACON Laboratories (k112653) and was designed according to CLSI EP7-A2 guideline. Interference Effect studies were performed on the On Call Blood Glucose Monitoring System and the identical strips are used with In Touch® Blood Glucose Monitoring System. 35 common endogenous and exogenous interfering substances were evaluated by spiking venous blood to three levels of glucose concentrations (50, 100, 350 mg/dL). The glucose samples were then spiked with the potentially interfering compounds (2 concentration including normal or therapeutic levels and high or toxic levels). Two meters were used for this study with 4 strips for each meter. Three lots of test strips were tested for a total of 1152 test strips. Bias was calculated as the mean percent difference in glucose reading between the test and control concentration groups. The sponsor claims no significant interference if bias between the tested and the control sample is <10% difference. A summary of the concentrations of the potential interfering substances tested is summarized in the table below:

Interfering Substances	Therapeutic/Physiological Levels, mg/dL	Test Levels	
		Low, mg/dL	*High, mg/dL*
Acetaminophen	1.0-3.0	4	20
Ascorbic Acid	0.4-2.0	3	6
Cholesterol	114-300	250	500
Conjugated Bilirubin	<0.4	34	50
Creatinine	0.6-1.3	1.5	5
Dopamine	0.03	0.03	0.09
Ephedrine	0.001	0.1	0.5
Ethanol	100-200	200	400
Fructose	1-6	30	100
Galactose	4-80	78	100
Gentisic Acid	0.2-0.6	6	10
Glutathione	47-100 (intracellular)	0.5	1
Hemoglobin	100-200	200	500
Ibuprofen	1.0-7.0	7	50
Lactose	0.5	5	25
L-Dopa (Levo-Dopa)	0.02-0.3	0.3	3
Maltose	100	40	100
Mannitol	0.0128	300	600
Methyl Dopa	0.1-0.75	0.75	1.5
Salicylic Acid	10-30	30	60
Sorbitol	0.044	30	70
Tetracycline	0.2-0.5	0.5	1.5
Tolazamide	2.0-2.5	5.0	10
Tolbutamine	5.4-10.8	11	64
Triglycerides	150-500	1500	3000

Interfering Substances	Therapeutic/Physiological Levels, mg/dL	Test Levels	
Unconjugated Bilirubin	0.3-1.3	20	40
Urea	6.6-85.8	260	600
Uric Acid	2.5-8.0	8	23.5
Xylose	20-40	90	200

Based on the study data, all the substances and levels tested above have <10% bias except for ascorbic acid > 3 mg/dL (above therapeutic levels). Ascorbic acid levels > 3 mg/dL will interfere with the glucose reading; therefore, the following limitation has been included in the labeling:

"Ascorbic acid (vitamin C) (when occurring in blood at normal or at high therapeutic concentration) do not significantly affect results. However, abnormally high concentration) in blood may cause inaccurately high results."

Operating Temperature and Humidity Study: This study confirmed the operation of the In Touch® Blood Glucose Monitoring System for the temperature range of 5-45ºC and the relative humidity range of 10-90%, noncondensing.

Robustness Evaluation: In Touch® demonstrated robustness to cleaning, disinfection, and handling under simulated conditions. The subject device was found to be substantially equivalent to the predicate device across the entire claimed measuring range, before and after the 1,825 cleaning cycles of cleaning and disinfection with Dispatch® Hospital Cleaner Disinfectant Towels with Bleach disposable wipes (EPA Reg. No: 56392-8).The In Touch® Blood Glucose Meter is robust to multiple cleaning and disinfection cycles under normal user simulated conditions of a 5 year period with no alteration in the physical, operational, mechanical, or analytical performance characteristics and meets the acceptance criteria for cleaning and disinfection.

Flex Studies: The In Touch® Blood Glucose Monitoring System was examined to test the operational limits of the system and to validate the insensitivity of the system to performance variation under stress conditions. Accordingly, the following were carried out:

1) Risk Analysis, a systematic and comprehensive risk analysis that has identified all potential sources of error, including test system failures and operator error. Control measures are identified including fail-safe and failure alert mechanisms;
2) Mechanical Vibration testing. Fifty (50) In Touch® devices were subjected to 0.7 mm amplitude, 1 cycle, 10-60 MHz, 2 minutes for a total of 1.5 hours;
3) Aging test at 43°C for 120 days. All studies showed the performance to be unaffected by vibration or aging.

Human Factors Studies: A number of ergonomic factors were tested with users including meter size, display size, the placement of buttons, height of the numerals, and meter carrying case. The studies show that users find In Touch® to be easy to use and that the ergonomic factors designed into the system reduce user error through clear display and easy to understand language. The usability testing and results were considered in the Risk Analysis. As problems were identified, both software and mechanical changes were made.

ISTA Standard 2A Transportation & Packaging: Testing demonstrated compliance with ISTA Standard 2A, Partial Simulation Performance Testing for Medical Devices.

Summary: All testing met acceptance criteria. The In Touch® Blood Glucose Monitoring System is substantially equivalent to the predicate devices that are subject to this 510(k) submission. The In Touch® Blood Glucose Monitoring System meets all the requirements for the overall design, disinfection/cleaning, biocompatibility and electrical safety and confirms that the output meets the design inputs and specifications. The In Touch® Blood Glucose Monitoring System passed all testing stated above as shown by the acceptable results obtained.

The In Touch® Blood Glucose Monitoring System complies with the applicable voluntary standards for biocompatibility and sterilization. The device passed all the testing in accordance with national and international standards.

11. Clinical Performance Characteristics

As part of demonstrating safety and effectiveness of In Touch® and to show substantial equivalence to the predicate devices, EosHealth completed the following clinical performance testing:

Lay Accuracy Evaluation (lay user): A system evaluation (Method Comparison of subject device verses a reference standard) of lay user accuracy and performance was performed on the In Touch® Blood Glucose Monitoring System per FDA's Draft Guidance *Total Product Life Cycle for Portable Invasive Blood Glucose Monitoring systems* and ISO 15917.

The user performance study demonstrated that lay consumers could obtain accurate results using the In Touch® Blood Glucose Monitoring System and meet the ISO 15197:2003 and ISO 15197:2013 accuracy standards, as well as meeting the current FDA standards (2003) and those proposed in the Guidance Document issued January 2014. The study was performed using capillary whole blood from fingertip sample sites.

Table 2: Summary of Lay Accuracy Studies

Lay User Fingertip Site: System Accuracy Results for Glucose Concentration ≥75mg/dL			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
68/93 (73.1%)	87/93 (93.5%)	92/93 (98.9%)	93/93 (100.0%)
Lay User Fingertip Site: System Accuracy Results for Glucose Concentration <75mg/dL			
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	
6/9 (66.7%)	9/9 (100.0%)	9/9 (100.0%)	

12. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

The information and data provided in this submission clearly describes the proposed device and demonstrates that the device is adequately designed for the labeled indication for use.

Performance, verification, and validation testing were conducted to characterize the performance of the proposed device and the predetermined acceptance criteria were met. Results of this testing have documented that the proposed device is substantially equivalent to the predicate device and is suitable for the labeled indication for use. The In Touch® Blood Glucose Monitoring System and the predicate devices do not raise any questions regarding its safety and effectiveness. The In Touch® Blood Glucose Monitoring System, as designed and manufactured, is substantially equivalent to the referenced predicate device.